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Der Präsident des Europäischen Patentamts;
im Auftrag

For the President of the European Patent Office

Le Président de l'Office européen des brevets
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Compositions and methods for promoting lipid assimilation in pets

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S P E C I F I C A T I O N

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Title**COMPOSITIONS AND METHODS FOR PROMOTING LIPID ASSIMILATION IN PETS****Field of Invention**

10 This invention relates generally to a food and/or food supplement product for pets and to its use in improving lipid absorption. In particular, it relates to improving lipid absorption in senior cats suffering the effects of pathologies and/or aging. The invention extends to methods of enhancing lipid digestibility and/ or assimilation in pet animals.

15 Background to the Invention

Studies on senior cat nutrition have shown that a significant number of older pets – such as those above the age of 9 years - exhibit a decreased capacity to digest fat. Several scientific publications have likewise reported an age-related decrease in lipid digestibility in cats (Burkholder, WJ. Age-related changes to nutritional requirements and digestive 20 function in adult dogs and cats. JAVMA, Vol 215, No. 5, September 1, 1999; Nicholson A, Watson ADJ, Mercer JR. Fat malassimilation in three cats. Australian Veterinary Journal, Vol. 66, No. 4, April, 1989; Peachey SE, Dawson JM, Harper EJ. The effects of aging on nutrient digestibility by cats fed beef tallow, sunflower oil or olive oil enriched diets).

25 There can be any of a number of pathologies that can lead to poor digestibility of lipids. Malabsorption and maldigestion can occur from almost any diffuse disease of the intestine, from exocrine pancreatic insufficiency or from unknown causes. In the case of cats, pancreatitis occurs at a prevalence rate of about 0.15% to 3.5% and may account for some cases of poor fat digestibility. Diffuse intestinal diseases, such as intestinal lymphoma, 30 small intestinal bacterial overgrowth, inflammatory bowel disease and liver disease, may also lead to reduced nutrient absorption in the small intestine.

35 Cases of pancreatic insufficiency are sometimes treated in veterinary practice by the addition of raw pancreas to the diet of the animal. The pancreas should not be heated to avoid denaturation of digestive enzymes. This kind of procedure is not convenient for the

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pet owner to have to perform on a regular basis. Commercially made enzyme supplements, for example as sold under the trade name Viokase V (believed to be a trade mark of Axcan Pharma US, Inc. of Birmingham, Alabama), are effective in improving fat digestibility in animals affected by pancreatic insufficiency, but they are expensive when given in the 5 requisite amounts. They are therefore unsuitable for inclusion in the regular diet of a pet.

Nicholson et al (op. Cit.) disclosed that dietary pancreatic extract supplementation of cats presenting with poor fat digestibility almost doubled fat digestibility, although enzyme supplementation failed to increase fat digestibility to normal levels in all three cats tested. 10 These findings point to pancreatic enzyme supplementation being able to achieve only partial correction.

Vitamins A, D, E and K are fat-soluble vitamins that are absorbed only with long chain fatty acids. A defect in either the absorption or digestion of lipid can therefore lead to 15 deficiencies in any of these vitamins, as well as malabsorption of nutrients such as taurine or minerals such as calcium and magnesium, due to their binding with unabsorbed fatty acids (Simpson, KW and Michel, KE. Micronutrient status in patients with gastrointestinal disease. Proceedings ACVIM, Denver, CO, pp. 651-653, 2001). Hence, a pet with low lipid digestibility is susceptible to several potential nutritional deficiencies, which can compromise 20 its health.

For purposes of this specification, the term lipid fraction should be understood to mean a group of compounds that are insoluble in water, the group embracing fats, oils, waxes, phosphatides, cerebrosides, sterol, terpenes and the like, most of these including a fatty acid in their structures. Lipids can function to carry or transport a nutrient from a food 25 source to the intestine and to the site of utilization, such as in a cell of the recipient's body.

"Digestion", as used in this specification, means the process of breaking down a complex food matrix into its constituent parts, for example fats to glycerol and fatty acids. The 30 breaking down process is primarily by action of gastric, hepatic and pancreatic enzymes.

"Absorption" as used in this specification, means the passage of the products of the breaking down process across the intestinal wall into the blood stream.

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"Digestibility", as used in this specification, means the quantity, expressed in percentage form, of a nutrient that is digested and absorbed in relation to the total nutrient quantity ingested by the animal.

5 "Assimilation", as used in this specification, means the process of incorporation of simple molecules, produced from food digestion and absorbed into the body, into the complex compounds forming the constituents of the organism.

10 It is thus an object of the invention to provide a nutritional product that, when administered to a pet displaying low lipid digestibility, improves the digestibility of lipid and lipid-linked compounds. Another object is to provide the pet and pet owner with advantages associated with effective lipid absorption.

15 A further object is to provide a complete pet food or supplement for a complete pet food that aids the pet to absorb lipid and lipid soluble nutrients in its diets.

Another object of the invention is to provide a method of improving lipid absorption in a pet animal, especially a senior pet.

20 A further object is to provide a means of improving the transportation of fat-soluble vitamins and essential fatty acids into the a pet's tissues.

Summary of Invention

25 The invention provides compositions and products that include them, for providing benefits related to the effective assimilation of a lipid or a lipid fraction. It also provides methods of improving or maintaining the capacity of a pet animal to assimilate a lipid or a lipid fraction effectively and to enable it to derive a benefit therefrom.

30 Therefore, according to the invention, a method of providing a pet with a benefit relating to effective assimilation of a lipid or lipid fraction comprises the steps of administering to the pet, as a part of, or in addition to, its regular diet, an edible composition that contains an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently.

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The said ingredient may be selected from the group consisting of:

- pancreatic function promoters
- liver function-promoters,
- intestinal mucosa function promoters and
- combinations thereof.

5 In an embodiment of the invention, the pancreatic function promoter is selected from lipases, gut pH modifiers, pancreatic extracts, and combinations thereof. In an embodiment wherein the pancreatic function promoter is a gut pH modifier, it may include one or more of 10 an acidifier, an alkaliniser, a buffer, a prebiotic or a probiotic micro-organism. The lipases may be natural or artificial.

15 In an embodiment, the liver function promoter is selected from taurine, emulsifiers, vitamins, minerals, glutathione and glutathione promoters, and combinations thereof.

20 In an embodiment, the liver function promoter is a nutrient that increases endogenous glutathione after ingestion.

25 In an embodiment, the intestinal mucosa function promoter includes a fat transportation aid, agent or carrier. The aid, agent or carrier may be selected from whey protein and proteases having the capacity to promote the formation of lipoproteins.

30 In an embodiment, the intestinal mucosa function promoter includes an anti-inflammatory agent, such as an omega-3 fatty acid, lactoferrin, a prebiotic or a probiotic microorganism or combinations thereof.

35 In an embodiment, the intestinal mucosa function promoter has a fatty acid profile specially selected to improve absorption. In a preferred such embodiment, the fatty acid profile is of a combination of long and medium chain triglycerides.

40 In a further embodiment, the fat transportation agent is whey protein.

45 In any of the above embodiments, the benefit derivable by the pet from effective assimilation of a lipid or lipid fraction may be related to:

- Gut function

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- Outward appearance
- The pet-to-owner relationship
- Aging; or
- General health aspects.

5

Where the benefit is related to gut function, it may be observed in any one or more of:

- Increased nutrient and energy digestibility;
- Improved gut microflora, such as is observed in decreased small intestine bacterial overgrowth;

10 - Improved fecal consistency and/or odor;

- Optimized fecal volume;

- Improved regularity of food transit time;

- Reduced flatulence;

- Enhanced gut detoxification; and

15 - Improved absorption of fat-soluble nutrients.

The fat-soluble nutrients are preferably fatty acids, certain antioxidants and vitamins A, D, E and K.

20 Where the benefit is related to outward appearance, it may be observed in any one or more of:

- Improved body condition;
- Improved muscle tone;
- Improved skin and coat condition; and

25 - A younger look.

Where the benefit is related to owner relationship it may be observed in any one or more of:

- Increased levels of physical activity;
- Improved pet-owner interaction;

30 - Improved pet-owner bonding;

- Increased playfulness; and

- Improved alertness, mental performance and / or cognitive ability.

Where the benefit is related to aging, it may be observed in any one or more of:

35 - Delayed onset of signs of aging;

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- Amelioration of an age-related effect;
- Improved vision;
- Restored functionality of the digestive system in an aged pet; and
- Increased longevity.

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Where the benefit is related to general health aspects, it may be observed in any one or more of:

- Improved nutritional status;
- Improved overall health status;
- Improved water turnover;
- Improved bioavailability of essential nutrients;
- Improved antioxidant status;
- Improved nitrogen balance;
- Reduced renal overload by reduction of proteolysis; and
- Improved functions associated directly or indirectly with improved absorption of lipids, energy and/or antioxidants.

The essential nutrients may include fatty acids and vitamins.

20 Improved antioxidant status may be achieved by increasing vitamin or antioxidant absorption, in particular, fat-soluble vitamin and antioxidant absorption.

In an embodiment, the composition is administered as a nutritionally balanced, ready-to-eat meal.

25

In a second aspect of the invention, a method of improving lipid absorption in a pet animal, especially a senior pet, comprises administering to it an edible composition comprising at least one ingredient selected from the group consisting of lipase, pancreas extracts, taurine, vitamins, enzymes or lecithin.

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In an embodiment of the invention, the lecithin is obtained from a source selected from soya, sunflower oil, wheat germ, avocado and combinations thereof.

35 In an embodiment of the invention, the liver function-promoter comprises a pancreas extract. In a preferred embodiment, the extract includes pancreatic lipase.

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In an embodiment of the invention, the pancreas extracts comprise lipase derived from a non-pancreatic source. In an embodiment, the non-pancreatic source is a fungus.

- 5 According to another aspect of the invention, an edible composition for use in maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal comprises a lipid assimilation-promoting ingredient for administering regularly, according to predetermined directions, to a pet animal.
- 10 In an embodiment, the composition is prepared in an industrial process and packaged as a ready-to-eat meal.
- 15 In an embodiment, the lipid assimilation-promoting ingredient is provided in a container for addition to a separately packaged complete meal or for administering apart from a meal. In an embodiment, the ingredient is provided in a pharmaceutically acceptable carrier.
- 20 In an embodiment, the ingredient is selected from the group consisting of pancreatic function promoters, liver function-promoters, intestinal mucosa function promoters and combinations thereof.
- 25 In a further aspect of the invention, a method of improving the capacity of a pet animal to absorb an essential nutrient comprises the step of improving the capacity of the animal to absorb a lipid or lipid fraction that is a carrier of the essential nutrient. Preferred essential nutrients include vitamin E and arachadonic acid (or ARA).
- 30 The invention extends, in another aspect, to the use of a lipid digestibility-enhancing agent in the manufacture of a dietary composition or dietary supplement, for the provision of a benefit relating to optimal lipid absorption in a pet animal. The benefit may be any one of those listed above.
- 35 According to another aspect of the invention, a method of improving the appearance of a pet comprises the step of increasing its capability to digest fat in its diet: wherein fat digestion capability is increased by feeding the pet a diet that contains an agent selected from:
 - a fat emulsifier / emulsification system

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- an acidifying agent
- a fat transportation agent (whey protein as a carrier for lycopene), and
- combinations thereof.

5 The invention extends to a method of improving or maintaining absorption of vitamin E in a pet animal, the method including the step of feeding the pet an edible composition that promotes or maintains or improves its lipid absorption capacity.

10 According to a further aspect, a method of maintaining or improving the serum vitamin E level in a pet animal comprises the step of administering the pet animal an edible composition that promotes or maintains or improves its lipid absorption capacity. Preferably, administration is by feeding the pet a food product that includes the ingredient.

15 In embodiments of these methods, the ingredient is selected from the group consisting of pancreatic function promoters, liver function-promoters, intestinal mucosa function promoters and combinations thereof.

20 The invention provides also for a composition for use in a method of maintaining promoting or improving serum levels in a pet animal of essential fatty acids and /or fat soluble antioxidants, the composition comprising an agent selected to promotes or maintain or improve lipid absorption capacity of said pet and the method comprising administering the composition orally to the pet according to a predetermined dietary regimen. The agent is preferably selected to maintain, promote or improve serum levels of arachadonic acid and/ or linoleic acid.

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In a still further aspect of the invention, a nutrition management regimen for maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal comprises a dietary component for administering regularly, according to predetermined directions, to such pet animal, the dietary component comprising an effective amount of a lipid 30 assimilation-promoting ingredient or a lipid digestibility enhancing ingredient selected from the group consisting of a pancreatic function promoter, a liver function-promoter, an intestinal mucosa function promoter and combinations thereof.

An advantage of the invention is that it produces visible improvements in the body condition 35 of senior pets, such as fragile senior cats.

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Another advantage is that it provides an improvement of their nutritional status. Through this, there are further benefits expected, such as improvement in the quality of life and extended longevity of the pet and greater satisfaction of the owner.

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A still further advantage of the invention is that it may be applied not only to clinically healthy senior pet cats, but also to cats with Exocrine Pancreatic Insufficiency (EPI) and a wider range of digestive deficiencies that contribute to lipid malabsorption, for which the mechanisms are not yet fully understood.

10

Brief Description of Accompanying Drawings

Figure 1 is a graph tracking the relationship between lipid digestibility and serum vitamin E level in pet cats.

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Detailed description of embodiments

It has been found that in pet animals, the absorption of lipid is highly correlated with the absorption of other essential nutrients, for example vitamin E. Hence, a pet with low lipid digestibility is susceptible to deficient or sub-optimal nutritional status, which can compromise its health.

This invention seeks to provide means of prevention and relief for pets that are susceptible to develop, or that have already developed, reduced lipid absorption capability from any cause. Such a cause may include EPI, inflammatory liver disease, pancreatitis, inflammatory bowel disease, intestinal lymphoma, and idiopathic (unknown cause) malabsorption. The invention provides a means for increasing lipid absorption through nutrition management. Such management can be carried out by the pet owner, care giver or keeper. By implementing it as a regimen that maintains, improves, promotes or otherwise enhances lipid digestibility, various health and wellness benefits can ensue. These are set out more fully below.

Thus, a nutrition management regimen for maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal, comprises a lipid absorption-promoting ingredient for feeding regularly to the pet animal in need thereof, according to

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predetermined directions. The lipid absorption-promoting ingredient comprises at least one nutrient selected from the groups comprising pancreatic function promoters, liver function promoters, intestinal mucosa function promoters and combinations thereof. It may be administered as a part of its regular diet, such as in the medium of a nutritionally balanced pet food or as a supplement to a meal or to a treat.

5 The pet may be a cat or a dog. The invention has particular advantage for elderly or senior pets. Generally, these are pets of age 9 years and above.

10 Pancreatic function promoters that may be used in this invention include natural and artificial lipases, gut pH modifiers, pancreatic extracts, and combinations thereof. Advantageously, where the pancreatic function promoter is lipase enzyme, it is present to be administered to the pet in an edible composition in an amount sufficient to provide the pet receiving it with from about 1,000 to 80,000 IU of lipase enzyme daily. Preferably, the 15 composition contains sufficient amount of the promoter to provide from about 9,000 to 60,000 IU of lipase enzyme daily, when administered according to a predetermined regimen.

20 Where the pancreatic function promoter is a gut pH modifier, it may comprise a system that includes one or more of an acidifier, an alkalinizer, a buffer, a prebiotic or a probiotic micro-organism. Preferred gut pH modifiers are those that promote fermentation and modify gut pH in a predictable and controllable manner. Examples of suitable acidifiers are citric acid and lactic acids. An example of a suitable base is sodium hydroxide. The base may also be a carbonate or bicarbonate or include combinations thereof.

25 In embodiments where the gut pH modifier is an acidifier, it should be provided to be present in sufficient amount to reduce the gut pH by about 1 point on the 14 point pH scale.

30 In embodiments where the gut pH modifier is an alkalinizer, it should be provided to be present in sufficient amount to increase the gut pH by about 1 point on the 14 point pH scale.

Where the gut pH modifier is a buffer, it should be provided to be present in sufficient amount to maintain gut pH below about 4 during the initial stages of digestion.

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Where the pancreatic function promoter is a pancreatic extract, the extract preferably includes pancreatic lipase. However, lipase derived from a non-pancreatic source may, in addition or alternatively, be used.

5 In preferred embodiments of the invention, the gut pH-modifying agent is a prebiotic or a probiotic micro-organism, or a combination thereof. The prebiotic may be obtained from any suitable natural or purified source, for example chicory, and may comprise inulin or an oligosaccharide. Should a probiotic microorganism be selected, it needs to be one that, via 10 fermentation processes in the gut, regulates the gut pH. In general, probiotic microorganisms produce organic acids such as lactic acid and acetic acid which inhibit the growth of pathogenic bacteria such as *Clostridium perfringens* and *Helicobacter pylori*. Examples of suitable probiotic micro-organisms include yeasts such as *Saccharomyces*, *Debaromyces*, *Candida*, *Pichia* and *Torulopsis*, molds such as *Aspergillus*, *Rhizopus*, *Mucor*, and *Penicillium* and *Torulopsis* and bacteria such as the genera *Bifidobacterium*, 15 *Bacteroides*, *Fusobacterium*, *Melissococcus*, *Propionibacterium*, *Enterococcus*, *Lactococcus*, *Staphylococcus*, *Peptostreptococcus*, *Bacillus*, *Pediococcus*, *Micrococcus*, *Leuconostoc*, *Weissella*, *Aerococcus*, *Oenococcus* and *Lactobacillus*. Specific examples of suitable probiotic microorganisms are: *Saccharomyces cerevisiae*, *Bacillus coagulans*, *Bacillus licheniformis*, *Bacillus subtilis*, *Bifidobacterium bifidum*, *Bifidobacterium infantis*, 20 *Bifidobacterium longum*, *Enterococcus faecium*, *Enterococcus faecalis*, *Lactobacillus acidophilus*, *Lactobacillus alimentarius*, *Lactobacillus casei* subsp. *casei*, *Lactobacillus casei Shirota*, *Lactobacillus curvatus*, *Lactobacillus delbrueckii* subsp. *lactis*, *Lactobacillus farcininus*, *Lactobacillus gasseri*, *Lactobacillus helveticus*, *Lactobacillus johnsonii*, *Lactobacillus reuteri*, *Lactobacillus rhamnosus* (*Lactobacillus GG*), *Lactobacillus sake*, 25 *Lactococcus lactis*, *Micrococcus varians*, *Pediococcus acidilactici*, *Pediococcus pentosaceus*, *Pediococcus acidilactici*, *Pediococcus halophilus*, *Streptococcus faecalis*, *Streptococcus thermophilus*, *Staphylococcus carnosus*, and *Staphylococcus xylosus*. The probiotic microorganisms may be in powdered, dried form; especially in spore form for 30 microorganisms which form spores. Further, if desired, the probiotic microorganism may be encapsulated to further increase the probability of survival; for example in a sugar matrix, fat matrix or polysaccharide matrix. Alternatively, the microorganism may be provided as a separately contained supplement to the main food composition.

35 In an embodiment of the invention, a combination of any of the above two or more pancreatic function promoters may be used.

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5 Liver function promoters suitable for use in this invention may be selected from edible emulsifiers, taurine, glutathione or glutathione promoters, minerals and vitamins. The taurine used may be natural or from a purified source or may be a mixture of both. In embodiments of the invention where the composition of the invention is made available in the form of a dry pet food, taurine is included at up to about 0.5% by weight on a dry matter (DM) basis. In preferred embodiments, the taurine concentration is in the range from about 0.1% to about 0.4% by weight on a DM basis. In the case of a wet (canned) pet food, the taurine concentration may be up to 1% by weight on a dry matter basis, but is preferably no 10 more than about 0.8% on a DM basis, by weight.

15 Non-limiting examples of glutathione promoters are selenium and vitamin E. In preferred embodiments, selenium is present at about from 2 to 3 times the Association of American Feed Control Officials (AAFCO) minimum. For example, there may be about 0.3mg selenium per kilogram of diet on a DM basis. Vitamin E levels may be up to about 20 times the AAFCO minimum, for example currently up to about 600 IU on a DM basis. These agents may be obtained from natural or purified sources and may comprise combinations of both.

20 In an embodiment, the liver function promoter is a nutrient that is capable of increasing endogenous glutathione after ingestion.

25 The liver function promoter may also be an edible emulsifier. A preferred example is lecithin, which may be obtained from a source such as soya, sunflower oil, wheat germ, egg, avocado and combinations thereof. In preferred embodiments, the composition includes up to about 1% by weight of lecithin on a DM basis when administered in pet food form, or provides up to about 1% of lecithin in the diet, when determined on a DM basis.

30 Where the liver function promoter is a vitamin, it may for example be obtained from a natural source, for example yeast, or a purified source, or combinations thereof. In preferred embodiments, the composition of the invention comprises a selected vitamin in sufficient amount to exceed the minimum level set from time to time by AAFCO by about 2 to 5 times (in other words about 200-500% of the AAFCO minimum).

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Similarly, minerals used for promoting liver function are obtainable from natural or purified sources and combinations thereof. In preferred embodiments, the composition of the invention comprises a selected mineral in sufficient amount to exceed the minimum level set from time to time by the Association of American Feed Control Officials (AAFCO) by about 5 to 6 times (in other words about 300% to 500% of the AAFCO minimum).

Advantageously, the liver function promoter is present to be administered to the pet in an edible composition in an efficacious amount when administered according to a predetermined regimen, in order to obtain at least one of the benefits set out below.

10

The intestinal mucosa function promoter of the invention may, in an embodiment, include a fat transportation aid agent or carrier, such as whey protein or a protease to help the formation of lipoproteins. An example of a suitable protease is papain. The diet or dietary composition may preferably comprise from about 0.1% to 1% by weight of papain on a DM basis. Should whey protein be included as a lipoprotein formation promoter, it is preferably present in concentrations from about 5% to 7% by weight of the diet on a DM basis.

20

The intestinal mucosa function promoter may, however, alternatively or in addition, include an anti-inflammatory agent. Suitable examples of these are the omega-3 fatty acids, lactoferrin, prebiotics, probiotic micro-organisms or fatty acids that have a profile specially selected to improve absorption. By way of example, a fatty acid group with a suitable absorption-enhancing profile is the medium chain triglycerides. In preferred embodiments, these are included in the diet at about 2% to 5% by weight of the diet on a DM basis.

25

Advantageously, the intestinal mucosa function promoter is present to be administered to the pet in an edible composition in an efficacious amount when administered according to a predetermined regimen in order to obtain at least one of the benefits set out below.

30

Where the intestinal mucosa function promoter comprises an omega 3 oil, it is preferably included in the diet from about 1% to 3% by weight on a DM basis. Where the diet or composition comprises lactoferrin, it is preferably included from about 100mg to 200mg per day. In the case of chicory, in preferred embodiments, it comprises from about 0.5% to 2% by weight of the diet or dietary composition on a dry matter basis. Prebiotics, for example inulin and/or oligosaccharides, should preferably make up from about 0.1% to 1% by weight

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of the diet on a DM basis. Probiotics, when included, are preferably at a numerical concentration of at least about 10^6 CFU in the diet.

5 The benefits that the feeding of the composition of the invention achieves in a pet, may be related to gut function, outward appearance, aging, or to more general health aspects.

Benefits relating to gut function include

- Increased nutrient and energy digestibility,
- Improved gut microflora as may be manifest in decreased small intestine bacterial overgrowth ("SIBO"),
- 10 - Improved fecal consistency and less offensive odor,
- Optimal fecal volume,
- Reduced flatulence,
- Improved gut detoxification, and
- Improved regularity of food transit time.

15

Appearance related benefits may include

- Improved body condition and muscle tone,
- Improved skin and coat condition, brought about by improving the bioavailability of required nutrients, such as fatty acids and vitamins, and
- 20 - Improving the overall appearance of senior pets by making them look younger.

Aging related benefits may include:

- A delayed onset of signs of aging,
- Reduction or amelioration of the effects of aging,
- 25 - Restoration of functionality of the digestive system in the aged pets, and
- Increased longevity.

30 The signs of aging may, for example, be appearance-related, such as greying of the coat, or activity-related, such as lower levels of activity. The effects of aging may be related to movement, such as apparent joint stiffness, or digestion-related, or reduction of sensory capacity and the like.

Owner-interaction benefits may include

- Improved physical activity,
- 35 - Increased level of playfulness,

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- Improved alertness, mental performance and cognitive ability, and
- Improved pet-owner interaction and bonding through increased activity and playfulness of the pet.

5 More general health benefits that are provided by the invention include

- Improved water turnover,
- Improved nutritional and overall health status,
- Improved antioxidant status by increasing vitamin (for example vitamin E) absorption,
- Improved nitrogen balance,

10 - Improved absorption of all lipid-soluble nutrients, for example fatty acids, vitamins A, D, E and K,

- Reduced renal overload by reduction of proteolysis, and
- Improved functions associated directly or indirectly with improved absorption of fat or antioxidants.

15 The invention thus also provides a method of reducing the effects of lipid malassimilation in a pet. The steps of this method may include administering to the pet a diet comprising an effective amount of an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently. The ingredient may be selected from those named above and

20 belonging to the general categories of pancreatic function promoters, liver function-promoters and intestinal mucosa function-promoters.

25 By improving the capacity of a pet animal to absorb a lipid or lipid fraction that is a carrier of an essential nutrient, the capacity of the animal to absorb the essential nutrient is also improved. The essential nutrient is typically a vitamin such as vitamin A, E, D, or K. Preferred nutrients include vitamin E and arachidonic acid (ARA). Through enhanced absorption efficiency of these nutrients, for example vitamin E, the serum level thereof may be maintained and/or improved. Figure 1 illustrates the relationship that has been found to exist between fat digestibility, expressed as a percentage (%), and serum vitamin E (µg/ml).

30 The digestibility enhancing ingredient or agent may be used in a method of manufacturing a dietary composition or supplement or pharmaceutical composition for providing benefits associated with optimal lipid absorption in a pet animal, or for the prophylaxis of conditions associated with poor lipid absorption and low digestibility. Such methods are described

35 further in the paragraphs that follow.

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The lipid assimilation or digestion-promoting ingredient, whether provided alone or in an ingredient combination or in a system of synergistic ingredients, may be provided for administering to a pet animal in need thereof in any of a number of different forms. For 5 example, it may be fed to the pet as part of a ready-to-eat meal or as part of a treat. Where provided as a pet food meal, the pet food of the invention may be produced in wet or dry form, using any suitable process. Preferably, the ingredients will be part of a nutritionally balanced meal. They may also be provided as a treat for feeding in addition to regular meals, or as a dietary supplement or complement that may be administered with a meal or 10 a snack or treat. The ingredient or ingredients may also be administered in a pharmaceutical form, the ingredient being contained in a pharmaceutically acceptable carrier. Such forms include tablets, capsules, syrups, drinks and gels and the like, in which the ingredients are suitably storable until the occasion of use.

15 Where, in a non-limiting example, ingredients are provided in the form of a pet food in wet form, it may be delivered as an emulsion gel or as solid pieces in a flowable gravy or gel.

Thus, to produce a thermally gelled emulsion that will set upon cooling, a suitable meat material is comminuted to produce a meat batter. Suitable gelling agents, for example 20 starches and gums such as kappa-carrageenan, locust bean gum, guar gum, and xanthan gum may be added to the meat batter. Usually no more than about 1% by weight of gum is needed.

25 Water may also be added to the meat batter to provide from about 70% to about 85% by weight of moisture. If sufficient moisture is present in the meat material, water need not be added.

30 The meat batter is then heated to a temperature suitable to initiate thermal gelling of the mixture; for example a temperature of about 40°C to about 65°C in a mixer-cooker. Steam may be injected into the meat batter if desired. The heated meat batter may be emulsified if desired. The meat batter is then maintained at a temperature of about 40°C to about 65°C until needed. After retorting and cooling to room temperature, the meat batter forms a thermally gelled emulsion that is substantially solid or at least holds its form.

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To produce solid food pieces in gravy or gel, solid pieces of meat or other material, or both, may be mixed with a gravy. Solid pieces of other materials may also be used; such as rice grains, pasta or noodles, vegetable pieces, and the like.

- 5 The solid food pieces may be in the form of pieces of a thermally gelled matrix. The pieces of the thermally gelled matrix may be produced by any suitable procedure, for example the procedures described in any one of US patents 4,781,939, 5,132,137 and 5,567,466 and PCT application WO 97/02760.
- 10 The thermally gelled matrix may be formed in suitable equipment such as an emulsion mill or an extruder to form pieces or chunks. If an extruder is used, the emulsion may be forced through an orifice to provide the emulsion with a desired shape; for example of oval, square or rectangular cross-section. The extrudate may then be cooked in a suitable continuous cooking system; for example a tunnel oven using hot air, steam, mixtures of hot air and steam, or microwaves as the heating medium. The core temperature of the extrudate is raised such that the extrudate undergoes thermal gelling. For example, the core temperature may be raised to at least about 80°C; for example about 85°C to about 95°C. The gelled extrudate may then be cut into pieces and the pieces cooled to provide pieces of a thermally gelled matrix. The pieces may be subjected to flaking if desired. Cooling may
- 15 20 be carried out by spraying water on the pieces. Alternatively, other cooling media may be used.

If a gravy is used with the solid food pieces, it may be produced from water, one or more starch or gums, and suitable flavoring agents. The gravy preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and gravy. Suitable gums are kappa-carrageenan, locust bean gum, guar gum and xanthan gum.

If a gel is used with the solid food pieces, it may be produced from a suitable gelling agent, water and suitable flavoring agents. The gel preferably comprises about 20% to about 80% by weight of the mixture of solid pieces and gravy. Suitable gelling agents are proteins such as gelatin; gums such as alginates, kappa-carrageenan, locust bean gum, guar gum and xanthan gum, and the like. The gel or aspic may be prepared as is conventional.

30 35 Combinations of the processes described above may also be used. For example, a thermally gelled emulsion may be prepared as described above. Then solid food pieces,

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which may be pieces of a thermally gelled matrix, meat pieces, vegetable pieces, combinations of these pieces, and the like, are combined with the thermally gelled emulsion. As a further alternative, combinations of thermally gelled emulsions and solid food pieces in gravy or gel, may be used. Suitable combinations are described in WO 5 98/05218 and WO 98/05219; the disclosures of which are incorporated by reference.

The pet foods are then filled into cans or other containers, the containers sealed, and the products reported in the normal manner. Suitable equipment is commercially available.

10 A suitable process for manufacturing dried pet food involves cooking a feed mixture of the various ingredients, forming the cooked mixture into pellets, drying, and then coating the pellets with flavors. The cooking and forming steps are preferably carried out using an extruder, as is well known in the art. However, the pellets may be produced by other cooking procedures such as baking a preformed food body comprising the selected 15 ingredients, preferably in nutritionally balanced proportions.

Whichever process is utilized, the lipid assimilation-promoting ingredient may be added at a suitable stage. Whichever stage is decided on may depend on the nature of the ingredient. It may be added to the major ingredients prior to the cooking, heating or extrusion stages, 20 or, in the case of heat-sensitive ingredients, may be added after the pieces have already formed, whether they be wet or dry. The ingredient may be absorbed into the food body, to be contained therein, or be injected, or be coated to remain largely on the surface. It may be included in the gravy that may accompany a gelled or extruded chunk, or be provided as a meal supplement.

25 Generally, application of the functional ingredient in a post-kibble formation step is carried out after the extrusion, drying and cooling process stages. The pet food kibbles enter a coating station, equipped for example with a coating drum. Here one or several coating systems are applied in liquid and/or in powder form to adjust the nutritional profile to 30 physiological and legal requirements, by including or adding such ingredients as required vitamins, fat, minerals and trace elements, to enhance the product palatability and to improve product cosmetics.

35 The amount of the pet food to be consumed by the pet to obtain a beneficial effect will depend upon factors such as the size or the pet, the type of pet, activity level and the age of

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the pet. However, an amount of the nutritional composition to provide a daily amount of about from 10g/kg to 25g/kg of body weight of the pet, on a dry matter basis, should be administered. Preferably, the amount should be in the range from about 12.5g/kg to 20g/kg of body weight on a DM basis in the diet.

5

Accordingly, the appropriate amount of the ingredient may then be included in the meal or treat, according to the pet's dietary requirements. The ingredient may be mixed in with the base formulation and then processed, or mixed into a gravy or other carrier for including with or adding to the food or treat.

10

It is believed that by providing a pet food composition as provided for above, making it available to minders or owners of elderly pets and drawing attention to the prospect that regular feeding of the composition to such pets can bring about at least a temporary alleviation of symptoms indicative of poor lipid assimilation in their pet, the pet minder will 15 be encouraged to administer the pet the composition on a regular basis. A suitable way of drawing the attention of the minder to the benefits of the composition is by way of notice on the packaging of the food composition, alternatively by separate advertising thereof.

20 Numerous modifications may be made to the embodiments described above without departing from the scope of the invention. By way of example, and not limitation, trials of products of the invention will now be described for further illustration:

Example

25 A series of digestibility tests is used to scan which nutritional interventions among numerous possibilities may improve the fat digestibility of cats pre-selected for their low fat digestibility (i.e. below 80%) when added to a control cat food diet.

Lipid digestibility is assessed on a group of cats using materials and methods as follows:

- All participating cats are adults and in good health and are not pregnant.
- 30 • Each test diet is the only source of nourishment for the cats.
- Water is available to the cats at all times.
- Each cat's weight is recorded prior to the initiation of the test.
- Each cat is fed the amount of food required to cover its metabolizable energy requirements.
- 35 • The cats are fed the same control diet for a feces pre-collection period of 5 days.

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- Each cat's weight is recorded at day 6.
- The fecal collection period is from day 6 through 15. The food consumed during this period is recorded.
- On day 6, the diet is fed together with red iron oxide as a marker, at a concentration of 5 1.0g/kg of meal mass for canned diets and 2.5g/kg of meal mass for dry diets.
- Red marked feces are the first to be collected. Any unmarked (normal colored) feces on day 6 and 7 prior to the first appearance of the red marked feces are discarded. All red marked feces are collected, as well as all unmarked feces that are passed after the first red feces are observed.
- 10 • Collected feces for each cat are stored frozen at ~ 20°C.
- On the morning of day 15, red iron oxide is again added to the diet (as in day 6), this time to mark the end of the trial feeding period, and the weight of each cat is recorded. Feces continue to be collected until the reappearance of the red marker.
- 15 • Two samples of the diet and each individual cat's fecal samples are freeze dried and sent for analyses of protein, fat, dry matter, and ash.

Examples illustrating the implementation of fat absorption-improving nutritional intervention into commercial pet food products are now described:

20 **Example 1: Trial using a canned food diet**

In this example, participating cats receive an emulsion meat diet, having a composition of about 9% fat, 2.2 % ash, 8.4% protein, and 76% moisture. This is called diet A.

25 Another diet, called B, is based on a similar formulation, but with the inclusion of the following additional ingredients:

- A pancreatic function promoter: 0.1% Acidifier (citric acid).
- A Liver function promoter: at about 4 x AAFCO minimum taurine level for wet cat food (0.8% by weight on a dry matter basis)
- An Intestinal mucosa function-promoter: Fish oils (3%)

30 A group of 20 cats with low fat digestibility (i.e. less than 80%) is fed both diets, A and B, in a crossover design of two digestibility tests. Each diet is fed for a 15-day digestibility test, the first 5 days being an adaptation period and the remaining 10 days as the fecal collection period. The cats are found to digest a significantly higher percentage of fat when fed diet B 35 than when fed diet A. As a result, total energy digestibility and organic matter digestibility is

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improved in diet B. Cats are found to need a lower amount of diet B to cover their energy requirements than of diet A. Overall, cats appear to maintain their weight better when fed diet B than when fed diet A.

5 **Example 2: Trial using a dry food diet.**

This example uses a conventional dry cat food having a composition of about 31% protein, 15% fat, 4.5% fiber, 12% moisture and 5% ash, called diet C.

10 Another diet, called D, was based on a similar formulation but the following additional ingredients were included:

- A pancreatic function promoter: Lipases (0.15%).
- A Liver function promoter: Lecithin from Soya (1%)
- An Intestinal mucosa function promoter: Chicory (1%)

15 In this trial, a group of 20 cats with known low fat digestibility (i.e. less than 80%) is fed diets C and D, in a crossover design of two digestibility tests. Each diet is fed for a 15-day digestibility test, the first 5 days being an adaptation period and the remaining 10 days the fecal collection period. The cats on diet D are found to digest a higher percentage of lipid than those on diet C. Total energy digestibility and organic matter digestibility are also 20 improved with diet D, when compared with diet C. Reduced fecal volume and odor were noted when cats were fed diet D instead of diet C.

25 It should be understood that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications can be made without departing from the spirit and scope of the present invention and without diminishing its intended advantages. It is therefore intended that such changes and modifications be covered by the appended claims.

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Claims

- 1 A method of providing a pet with a benefit relating to effective assimilation of a lipid or lipid fraction comprises the steps of administering to the pet, as a part of, or in addition to, its regular diet, an edible composition that contains an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently.
2. A method according to claim 1 wherein the ingredient is selected from the group consisting of:
 - pancreatic function-promoters
 - liver function-promoters,
 - intestinal mucosa function-promoters and
 - combinations thereof.
3. A method according to claim 2 wherein the pancreatic function-promoter comprises a lipase, a gut pH modifier or a pancreatic extract.
4. A method according to claim 2 wherein the liver function-promoter is selected from taurine, emulsifiers, vitamins, minerals, glutathione and glutathione promoters, and combinations thereof.
5. A method according to claim 2 wherein the intestinal mucosa function promoter includes a fat transportation aid, agent or carrier.
6. A method according to any one of the preceding claims wherein the benefit to the pet is related to at least one of gut function, outward appearance, pet-to-owner relationship, aging and general health aspects.
7. A method according to claim 6 wherein the benefit is related to aging, and is observable in any one or more of:
 - Delayed onset of signs of aging;
 - Amelioration of an age-related effect;
 - Improved vision;
 - Restored functionality of the digestive system in an aged pet; and

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- Increased longevity.

8. A method according to any one of the preceding claims wherein the composition is administered as a nutritionally balanced, ready-to-eat meal.

5

9. A method according to any one of the preceding claims wherein the composition is administered as a meal supplement.

10. A method according to claim 6 wherein the benefit is related to outward appearance and is observable in any one or more of:

- Improved body condition;
- Improved muscle tone;
- Improved skin and coat condition; and
- A younger look.

15

11. A nutrition management regimen for maintaining, improving, promoting or otherwise enhancing lipid digestibility comprises a dietary component for feeding regularly, according to predetermined directions, to a pet animal, the dietary component comprising a lipid assimilation-promoting ingredient.

20

12. A regimen according to claim 11 wherein the lipid assimilation-promoting ingredient is

- A pancreatic function-promoter
- A liver function-promoter,
- An intestinal mucosa function-promoter or
- A combination thereof.

25

13. A regimen according to claim 12 wherein the pancreatic function-promoter comprises a lipase, a gut pH modifier or a pancreatic extract.

30

14. A regimen according to claim 13 wherein the gut pH modifier includes one or more of an acidifier, an alkalinizer, a buffer, a prebiotic or a probiotic micro-organism.

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15. A regimen according to claim 12 wherein the liver function-promoter is selected from taurine, emulsifiers, vitamins, minerals, glutathione and glutathione promoters, and combinations thereof.

5 16. A regimen according to claim 12 or claim 15 wherein the liver function-promoter is a nutrient that increases endogenous glutathione after ingestion.

17. A regimen according to claim 12 wherein the intestinal mucosa function-promoter includes a fat transportation aid, agent or carrier.

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18. A regimen according to claim 17 wherein the aid, agent or carrier is selected from whey protein and proteases having the capacity to promote the formation of lipoproteins.

15

19. A regimen according to claim 17 or 18 wherein the intestinal mucosa function-promoter includes an anti-inflammatory agent, lactoferrin, a prebiotic or a probiotic micro-organism.

20

20. A regimen according to claim 19 wherein the anti-inflammatory agent is an omega-3 fatty acid.

21. A regimen according to claim 17 wherein the fat transportation aid, agent or carrier has a fatty acid profile specially-selected to improve absorption.

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22. A regimen according to claim 21 wherein the fatty acid profile is of a medium chain triglyceride.

23. A regimen according to claim 21 wherein the fat transportation aid, agent or carrier comprises whey protein.

30

24. A regimen according to any one of claims 11 to 23 wherein the benefit derivable by the pet from effective assimilation of a lipid or lipid fraction is related to at least one of gut function, outward appearance, pet-to-owner relationship, aging and general health aspects.

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25. A regimen according to claim 24 wherein the benefit that is related to gut function is observable in any one or more of:

- Increased nutrient and energy digestibility;
- Improved gut microflora, such as is observed in decreased small intestine bacterial overgrowth;
- Improved fecal consistency and/or odour;
- Optimized fecal volume;
- Improved regularity of food transit time;
- Reduced flatulence;
- 10 - Enhanced gut detoxification; and
- Improved absorption of fat-soluble nutrients.

26. A regimen according to claim 24 wherein the benefit that is related to outward appearance is observable in any one or more of:

- 15 - Improved body condition;
- Improved muscle tone;
- Improved skin and coat condition; and
- A younger look.

20 27. An edible composition for use in maintaining, improving, promoting or otherwise enhancing lipid digestibility in a pet animal comprising a lipid assimilation-promoting ingredient for administering regularly, according to predetermined directions, to a pet animal.

25 28. The composition of claim 27 wherein the ingredient is selected from the group consisting of pancreatic function-promoters, liver function-promoters, intestinal mucosa function-promoters and combinations thereof.

29. The composition of claim 27 or claim 28 wherein the ingredient is provided in a container for addition to a separately packaged complete meal or for administering apart from a meal.

30 30. A method of improving lipid absorption in a pet animal comprises administering to it an edible composition comprising at least one ingredient selected from the group consisting of lipase, pancreas extracts, taurine, vitamins, enzymes or lecithin.

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31. A method according to claim 30 wherein the pet is a senior pet.

32. A method according to claim 31 wherein the pet is at least 9 years old.

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33. A method according to claim 30 wherein the lecithin is obtained from a source selected from soya, sunflower oil, wheat germ, avocado and combinations thereof.

10 34. A method of improving or maintaining absorption of vitamin E in a pet animal, the method including the step of feeding the pet an edible composition that promotes or maintains or improves its lipid absorption capacity.

15 35. A method of maintaining or improving the serum vitamin E level in a pet animal comprising the step of feeding the pet animal an edible composition that promotes or maintains or improves its lipid absorption capacity.

20 36. A composition for use in a method of maintaining promoting or improving serum levels in a pet animal of essential fatty acids and /or fat soluble antioxidants, the composition comprising an agent selected to promotes or maintain or improve lipid absorption capacity of said pet and the method comprising administering the composition orally to the pet according to a predetermined dietary regimen.

37. A composition according to claim 36 wherein the agent is selected to maintain, promote or improve serum levels of arachadonic acid and/ or linoleic acid.

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ABSTRACT

A method of providing a pet with a benefit relating to effective assimilation of a lipid is described wherein the pet is administered, as a part of, or in addition to its regular diet, an edible composition that contains an ingredient that maintains, promotes or enhances the capacity of the pet to digest lipid efficiently. The invention extends to compositions for use in promoting lipid assimilation in pets, particularly senior or elderly pets. The compositions include pancreatic, liver and intestinal mucosa function-promoters. In embodiments, the liver function-promoter may be selected from taurine, emulsifiers, vitamins, minerals, glutathione and glutathione promoters.

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Figure 1

Relationship between Fat digestibility (%) and Serum Vitamin E (ug/ml).

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